Application No.: 10/783,522   Docket No.: MWS-109RCE

REMARKS

Claims 1, 5, 8, 11-16, 18-22, 28, 32 and 35 have been amended. Applicants note that all claim amendments are matters of form or address the §112 rejections. The claim amendments are not being made to distinguish over the prior art, and hence do not require a new search. Applicants therefore submit that the claim amendments should be entered and considered.

Now pending in the application are claims 1-36. Applicants have withdrawn originally filed claims 37-50 from further consideration by way of a previous response. Amongst claims 1-36, claims 1, 12, 22 and 28 are independent. The following comments address all stated grounds for rejection, and Applicants respectfully submit that the presently pending claims, as identified above, are now in a condition of allowance.

I.   Summary of Objections and Rejections

Claims 1-11 and 28-36 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

Claims 1-11 and 28-36 are rejected under 35 U.S.C. §101 as being drawn to non-statutory subject matter.

Claims 1-11 and 22-36 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

Claims 1-9, 22, 23, 25-27, 28-30 and 32-36 are rejected under 35 U.S.C. §102(b) as being anticipated by Goryanin et al. (Bioinfomatics, 1999, Vol. 15, No. 9, p.749-758).

Claims 1-2 and 10 are rejected under 35 U.S.C. §102(b) as being anticipated by DelaFuente et al. (Proceedings of the Second International Conference on System Biology, Pasadena, California, 2001, p213-221).

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Claims 12-19 and 21 are rejected under 35 U.S.C. §102(e) as being anticipated by Potts *et al.* (U.S. Patent No. 6,882,940).

Claims 1-2, 10-14, 20 and 21 are rejected under 35 U.S.C. §103(a) as being unpatentable over DelaFuente *et al.* in view of Bubendorf *et al.* (Journal of Pathology, 2001, Vol. 195, p.72-79).

These rejections will be discussed separately below.

II.   New Matter Rejections

Claims 1-11 and 28-36 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement." (See, the Office Action, page 3). Applicants respectfully traverse the rejection.

The Examiner alleges that (see the Office Action, page 3):

> Claims 1 and 28 have been amended to recite "instructions comprising: instructions for a simulation engine..." and "instructions for an analysis environment." ... However, the Examiner has not found support for these limitations in the specification, and these limitations are not present within the scope of the above claims as filed.

Applicants submit that the specification and drawings of the present application support the instructions recited in claims 1 and 28. Figure 1 of the present application shows a system (100) including a modeling environment (110), a simulation engine (120), and an analysis environment (130). The specification of the present application recites that "[t]he integrated system depicted in FIG. 1 may execute on a number of different computing platforms, such as supercomputers, mainframe computers, minicomputers, clustered computing platforms, workstations, general-purpose desktop computers, laptops, and personal digital assistants." (See page 6, lines 3-6). The specification of the present application also recites that "[t]he central processing unit 202 is any logic circuitry that responds to and processes instructions fetched from the main memory unit 204." (See page 6, lines 12-13). The figure and descriptions

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support the instructions recited in claim 1 and 28. Other features or languages of claims 1 and 28 are supported by the original claims, figures and specification of the present application. As such, Applicants request withdrawal of the rejection of claims 1-11 and 28-36 under 35 U.S.C. §112, first paragraph.

III.   Claim Rejections under 35 U.S.C. §101

Claims 1-11 and 28-36 are rejected under 35 U.S.C. §101 as being drawn to non-statutory subject matter." (See, the Office Action, page 4). Applicants respectfully traverse the rejection.

The Examiner alleges (see the Office Action, page 4) that:

> In the instant case, the claims ultimately result in "instructions for an analysis environment" and thus lack a tangible result as nothing is communicated to a user such that it is useful to one skilled in the art. For these reasons, the instant claims are not statutory.

Applicants have amended claims 1 and 28 to recite "saving the modified model in a storage." In view of the amendment, Applicants submit that the claims produce a tangible result, and hence are directed to statutory subject matter.

Furthermore, Claims 1 and 28 are directed to a medium holding instructions executable in a computing device. "When functional descriptive material is recorded on some computer-readable medium, it becomes *structurally* and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized (emphasis added)." MPEP §2106.01. The medium of claims 1 and 28 are structurally and physically changed when the instructions are recorded on the medium of claims 1 and 28. Applicants therefore submit that the claims are directed to statutory subject matter.

As such, Applicants respectfully request withdrawal of the rejection of claims 1-11 and 28-30 under 35 U.S.C. §101.

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IV.   Claim Rejections under 35 U.S.C. §112

Claims 1-11 and 22-36 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite. (See, the Office Action, page 5). Applicants respectfully traverse the rejection.

A.   Claims 1, 22 and 28

The Examiner asserts that "Claims 1, 22, and 28 now recite the limitation "experimental results generated by an in situ experiment conducted on a [*sic*] experimental device" in the preamble. It is unclear if applicant intends the functional limitation "generated by an in situ experiment..." to be an actual method step, a further limitation of the claimed method, or otherwise." (See the Office Action, page 5).

Applicants have amended claims 1, 22 and 28 to move the limitations previously recited in the preamble into the body of the claims. As such, Applicants request withdrawal of the rejection of claims 1, 22 and 28.

B.   Claims 5, 16 and 32

The Examiner asserts that "Claims 5, 16, and 32 recite the limitation "modeling environment." As the specification does not define or fully and completely describe 'environment,' it is unclear as to the metes and bounds intended by applicant for the claimed 'modeling environment.'" (See the Office Action, page 6).

Applicants submit that the term "environment" is well-known to those of ordinary skill in the art of computer science. The term "environment" may be used to refer to "[t]he set of resources made available to the user of a system." See Microsoft Press Computer Dictionary, Second Edition. The ordinary artisan may use the term "modeling environment" to refer to the resources that enable a user to model a system. As such, Applicants request withdrawal of the rejection of claims 15, 16 and 32.

C.   Claims 1 and 28

The Examiner asserts that "Claims 1 and 28 now recite 'instructions for a simulation engine generating an expected result.' It is unclear whether said instructions for simulation

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engine are intended to control said generating, or something else." (See the Office Action, page 6).

Applicants have amended claims 1 and 28 to clarify that the instructions generate an expected result. As such, Applicants request withdrawal of the rejection of claims 1 and 28.

The Examiner also asserts that "[c]laims 1 and 28 now recite 'instructions for an analysis environment..., said analysis environment gathering data...and comparing the expected result....' It is unclear whether said instructions for an analysis environment are intended to control said gathering and comparing, or something else." (See the Office Action, page 6).

Applicants have amended claims 1 and 28 to clarify that the instructions gather data and compare the expected result to the data. As such, Applicants request withdrawal of the rejection of claims 1 and 28.

D.   Claim 11

The Examiner asserts that "Claim 11 now recites the limitation 'wherein said analysis environment gathers data from a microarray.' As parent claim 1 is directed to a medium holding instructions, it is unclear if applicant intends for said 'gathers data from a microarray' to be an actual method step, a functional limitation of said analysis environment, or otherwise." (See the Office Action, page 6).

Applicants have amended claim 11 to recite instructions for gathering data from a gene chip. As such, Applicants request withdrawal of the rejection of claim 11.

In view of the foregoing amendment, Applicants respectfully request withdrawal of the rejection of claims 1-11, 22-36 under 35 U.S.C. §112, second paragraph.

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V. Claim Rejections under 35 U.S.C. §102(b) (Goryanin *et al.*)

Claims 1-9, 22, 23, 25-27, 28-30 and 32-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Goryanin *et al.* (Bioinfomatics, 1999, Vol. 15, No. 9, p.749-758). (See, the Office Action, page 7). Applicants respectfully traverse the rejection.

A.   Claims 1 and 28

Applicants respectfully submit that Goryanin *et al.* does not disclose at least the following feature of claims 1 and 28: "instructions for gathering data from an in situ experiment of the biological process conducted on an experimental device and comparing the expected result to the data gathered from said experimental device with an analysis component that is in communication with said simulation engine."

The Examiner alleges that "the feature argued by applicant is directed to an intended use, as claims 1 and 28 do not recite any instructions or active method steps directed to gathering data from an in situ experiment or conducting an experiment on an experimental device." (See, the Office Action, page 8). The Examiner also alleges that "the nature of experimental data (i.e. in situ data), per se, has no restrictive effect on the claimed medium." (See, the Office Action, page 8).

Applicants have amended claims 1 and 28 to clarify that the instructions gather data and compare an expected result to the data. The amendment also clarifies that the expected result is compared to the data gathered from an in situ experiment. In the claimed invention, the expected result is not just an observed or intended result, but a computer simulation result. Comparing the expected result to the data gathered from an in situ experiment is not an intended use, but a functional aspect of the instructions held in the medium. Applicants submit that Goryanin *et al.* does not disclose this functional feature. Furthermore, Goryanin *et al.* does not disclose instructions that when executed perform the functional feature.

Goryanin *et al.* does not disclose data gathered from an in situ experiment of a biological process conducted on an experimental device. Goryanin *et al.* discloses a mathematical simulation workbench, DBsolve, that helps create and analyze the mathematical models. (See, Goryanin *et al.*, Abstract). The Examiner alleges that "Goryanin et al. also teaches "simulation"

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of biological data (i.e. electronic experiments) [p.750, Col. 1, U 3], thus the computer itself is the experimental device." (See, the Office Action, page 8).

In comparison, the present application gathers data from an in situ experiment conducted on an experimental device. Goryanin *et al.* does not disclose "gathering data from an in situ experiment of the biological process conducted on an experimental device," as required by claims 1 and 28. Goryanin *et al.* is silent about an in situ experiment of a biological process conducted on an experimental device.

In view of the above arguments and the amendments to claims 1 and 28, Applicants respectfully request withdrawal of the rejection of claims 1 and 28.

B.   Claims 2-9, 29-30 and 32-36

Claims 2-9 depend on base claim 1 and, as such, incorporate all of the features of claim 1. Accordingly, claims 2-9 are allowable for at least the reasons set forth above with respect to claim 1. Applicants respectfully request withdrawal of the rejection of claims 2-9.

Claims 29-30 and 32-36 depend on base claim 28 and, as such, incorporate all of the features of claim 28. Accordingly claims 29-30 and 32-36 are allowable for at least the reasons set forth above with respect to claim 28. Applicants respectfully request withdrawal of the rejection of claims 29-30 and 32-36.

C.   Claim 22

Applicants respectfully submit that Goryanin *et al.* does not disclose at least the following features of claim 22: (1) "computer-readable program means for gathering data relating to an in situ experiment of the biological process conducted on an experimental device," and (2) "computer-readable program means for comparing the generated expected result to the data gathered from said experimental device."

As discussed above in section A, Goryanin *et al.* is silent about an in situ experiment of a biological process conducted on an experimental device. Goryanin *et al.* does not disclose "gathering data relating to an in situ experiment of the biological process conducted on an experimental device," and "comparing the generated expected result to the data gathered from

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said experimental device," which is present in claim 22. As such, Applicants respectfully request withdrawal of the rejection of claim 22.

D.   Claims 23 and 25-27

Claims 23 and 25-27 depend on base claim 22 and, as such, incorporate all of the features of claim 22. Accordingly, claims 22 and 25-27 are allowable for at least the reasons set forth above with respect to claim 22. Applicants respectfully request withdrawal of the rejection of claims 23 and 25-27.

VI.   Claim Rejections under 35 U.S.C. §102 (DelaFuente *et al.*)

Claim 1-2 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by DelaFuente *et al.* (Proceedings of the Second International Conference on System Biology, Pasadena, California, 2001, p213-221). (See, the Office Action, page 9). Applicants respectfully traverse the rejection.

A.   Claim 1

Applicants respectfully submit that DelaFuente *et al.* does not disclose at least the following feature of claim 1: "instructions for gathering data from an in situ experiment of the biological process conducted on an experimental device and comparing the expected result to the data gathered from said experimental device with an analysis component that is in communication with said simulation engine."

The Examiner notes that "the nature of experimental data, per se, has no restrictive effect on the claimed analysis environment." (See, the Office Action, page 10). Applicants have amended claims 1 and 28 to clarify that data may be gathered from an in situ experiment of the biological process conducted on an experimental device. Applicants submit that DelaFuente *et al.* does not disclose at least the feature of "gathering data from an in situ experiment of the biological process conducted on an experimental device," as is present in claim 1. DelaFuente *et al.* is silent about an in situ experiment.

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Applicants also submit that DelaFuente *et al.* does not disclose the feature of "comparing the expected result to the data gathered from said experimental device," as is present in claim 1. DelaFuente *et al.* is generally directed to a method for reverse engineering gene regulatory networks from microarray gene expression data. DelaFuente *et al.* discloses that the gene regulatory network is constructed from the measurement of gene expression ratios using microarray technologies. (See DelaFuente *et al.*, page 215, right column).

The Examiner asserts that "DelaFuente et al. also teach a software analysis environment (i.e. analysis environment) that compares theoretical data and regulatory strength values based on experimental microarray data, and a computer model (i.e. simulation engine) that takes in data and generates expected results [Table 1] and [p.216, Col. 2, fl 2]." (See the Office Action, page 9).

Applicants respectfully disagree with the Examiner's assertions. The portion of DelaFuente *et al.* referenced by the Examiner discloses a computer simulation of the reverse engineering method. (See DelaFuente *et al.*, page 215, right column). In Table 1, DelaFuente *et al.* discloses the comparison of the regulatory strength values obtained by Eq. 3, which are designated as "theoretical value," and the regulatory strength values obtained by the computer simulation of the reverse engineering method, which are designated as "1.1x perturbation," "0.5x perturbation," and "2x perturbation." DelaFuente *et al.* discloses Table 1 to show that the reverse engineering method proposed in DelaFuente *et al.* is acceptable compared with the theoretical method that uses Eq. 3. Furthermore, the values disclosed in Table 1 (1.1x perturbation, 0.5x perturbation, 2x perturbation) are produced by the computer-simulation of the reverse engineering method. DelaFuente *et al.* does not disclose comparing the simulation result of a model with in-situ experimental data.

In view of the above arguments and the amendments to claim 1, Applicants respectfully request withdrawal of the rejection of claim 1.

B.   Claims 2 and 10

Claims 2 and 10 depend on base claim 1 and, as such, incorporate all of the features of claim 1. Accordingly, claims 2 and 10 are allowable for at least the reasons set forth above with

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respect to claim 1. Applicants respectfully request withdrawal of the rejection of claims 2 and 10.

VII.   Claim Rejections under 35 U.S.C. §102 (Potts *et al.*)

Claims 12-19 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Potts *et al.* (U.S. Patent No. 6,882,940). (See, the Office Action, page 10). Applicants respectfully traverse the rejection.

A.   Claim 12

Applicants respectfully submit that Potts *et al.* fails to disclose "comparing, by an analysis environment, the generated expected result to data gathered from said experimental device," as is present in claim 12.

The Examiner alleges that "[c]laim 12 is now directed to a medium holding instructions executable in a computing device," and "the features argued by applicant are directed to an intended use." (See, the Office Action, page 10). Applicants submit that claim 12 is directed to a method, not a medium holding instructions executable in a computing device. Applicants also submit that the argued feature is an element of the method claim, not an intended use.

The Examiner also alleges that "Potts et al. teach microprocessors comprising programming (i.e, analysis environment) for comparing skin conductance readings (i.e. in situ experimental data) with threshold values (i.e. expected results) [Reference claims 1 and 25], as in instant claim 12." (See, the Office Action, page 10). Applicants submit that threshold value of Potts *et al.* is not the expected results present in claim 12.

Claim 1 of Potts *et al.*, which is referenced by the Examiner, recites "determining (i) a threshold glucose value that corresponds to said hypoglycemic event," and "comparing said predicted glucose measurement value to said threshold glucose value." Claim 25 of Potts *et al.*, which is also referenced by the Examiner, recites "compare said predicted glucose measurement value to a threshold glucose value." In Potts *et al.*, the threshold value is a predetermined value

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that is set to determine whether the predicted glucose measurement value is a hypoglycemic event or not.

In comparison, the expected result present in claim 12 may be generated by a simulation engine based on the execution of a model of a biological process. For example, the simulation engine may simulate the model of the biological process and generate the expected result from simulation of the model. The threshold value of Potts *et al.* is not generated from the simulation engine. The threshold value of Potts *et al.* is a predetermine value to predict a hypoglycemic event. (Column 3, lines 56-60). The threshold value of Potts *et al.* is not generated based on the simulation of the model of the biological process. As such, Potts *et al.* does not teach or suggest "comparing, by an analysis environment, the generated expected result to data gathered from said experimental device," where the expected result has been generated by a simulation engine based on the model of a biological process," as required by claim 12.

In view of the above, Applicants respectfully request withdrawal of the rejection of claim 12.

B. Claims 13-19 and 21

Claims 13-19 and 21 depend on base claim 12 and, as such, incorporate all of the features of claim 12. Accordingly, claims 13-19 and 21 are allowable for at least the reasons set forth above with respect to claim 12. Applicants respectfully request withdrawal of the rejection of claims 12-19 and 21.

VIII. Claim Rejections under 35 U.S.C. §103

Claims 1-2, 10-14, 20 and 21 are rejected under 35 U.S.C. §103(a) as being unpatentable over DelaFuente *et al.* (Proceedings of the Second International Conference on System Biology, Pasadena, California, 2001, p213-221), as applied to claims 1-2 and 10, in view of Bubendorf *et al.* (Journal of Pathology, 2001, Vol. 195, p.72-79). (See the Office Action, page 11). Applicants respectfully traverse the rejection.

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A. Claim 1

The Examiner relies on DelaFuente *et al.* to reject claim 1. (See the Office Action, page 12). DelaFuente *et al.*, however, does not teach at least the following feature of claim 1: "gathering data from an in situ experiment of the biological process conducted on an experimental device and comparing the expected result to the data gathered from said experimental device with an analysis component that is in communication with said simulation engine." As such, Applicants respectfully request withdrawal of the rejection of claim 1.

B.   Claims 2, 10-11

Claims 2 and 10-11 depend on base claim 1 and, as such, incorporate all of the features of claim 1. Accordingly, claims 2 and 10-11 are allowable for at least the reasons set forth above with respect to claim 1. Applicants respectfully request withdrawal of the rejection of claims 2 and 10-11.

C. Claim 12

Applicants respectfully submit that DelaFuente *et al.* and Bubendorf *et al.* do not teach or suggest "comparing, by an analysis environment, the generated expected result to data gathered from said experimental device," as present in claim 12.

The Examiner recognizes that DelaFuente *et al.* does not teach the use of an in situ experiment. (See, the Office Action, page 12). Bubendorf *et al.* is cited by the Examiner to provide teachings for an in situ experiment. Bubendorf *et al.* teaches Tissue microarray (TMA) technologies and in situ tissue analyses. (See Bubendorf *et al.*, Abstract). Although Bubendorf *et al.* teaches in situ experiments, Bubendorf *et al.* does not teach simulating a model of a biological process to generate expected results and comparing the results with data gathered from the in situ experiment. Therefore, Bubendorf *et al.* and DelaFuente *et al.*, alone or in any reasonable combination, do not teach or suggest gathering data relating to the experiment and comparing, by an analysis environment, the generated expected result to data gathered from said experiment, as present in claim 12.

In view of the above arguments and the amendments to claim 12, Applicants respectfully request withdrawal of the rejection of claim 12.

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D.   Claims 13, 14, 20 and 21

Claims 13, 14, 20 and 21 depend on base claim 12 and, as such, incorporate all of the features of claim 12. For reasons set forth above, Applicants respectfully submit that claims 13, 14, 20 and 21 are allowable. Applicants respectfully request withdrawal of the rejection of claims 13, 14, 20 and 21.
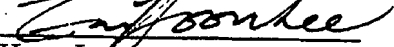
IX. Conclusion

In view of the above comments, Applicants believe that the pending application is in condition for allowance and urges the Examiner to pass the claims to allowance. Should the Examiner feel that a teleconference would expedite the prosecution of this application, the Examiner is urged to contact the Applicant's attorney at (617) 227-7400.

Please charge any shortage or credit any overpayment of fees to our Deposit Account No. 12-0080, under Order No. MWS-109. In the event that a petition for an extension of time is required to be submitted herewith, and the requisite petition does not accompany this response, the undersigned hereby petitions under 37 C.F.R. §1.136(a) for an extension of time for as many months as are required to render this submission timely. Any fee due is authorized to be charged to the aforementioned Deposit Account.

Dated: October 24, 2007   Respectfully submitted,

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